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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,692

Applicant(s)

WATANABE ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 20040416.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: IDS of 20040429; IDS of 20031229;and IDS of 20040401 .

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 5-7 of the amendment, filed September 28, 2004, with respect to the rejections of claims 12 and 16 under 35 U.S.C. 102(a) and the rejections of claims 1-11 and 13-15 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground of rejection is made in view of a patent issued after the mail date of the last Office action.

Status of Rejections Pending since the Office Action of June 29, 2004

2. All previous rejections are withdrawn.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 7 of U.S. Patent No. 6,773,564 meets all of the limitations of claim 1 of the instant application except that claim 7, nor any other claim in U.S. Patent No. 6,773,564, does not require the glucose sensor to be in a sealed container. Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of claim 1 of the instant application because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The sealed container will also prevent the reaction layer from being contaminated or wetted.

5. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 1, from which claim 2

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depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564 requires the reaction layer to contain phthalic acid.

6. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 4 and 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 1, from which claim 3 depends, has been addressed above. Claim 4 of U.S. Patent No. 6,773,564 requires the reaction layer to contain a calcium salt.

7. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 1, from which claim 4 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564 requires the reaction layer to contain gluconic acid, but does mention gluconic salts. As noted in the rejection of claim 1, Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also discloses that a gluconic salt, such as a sodium or potassium salt of gluconic acid may be used. See claim 4 of Akio. Since Akio discloses using a sodium or potassium salt of gluconic acid to preserve a glucose enzyme in a biosensor it would have been obvious to one with ordinary skill in the art at the time of the invention to also consider using it in the invention of claim 7 of U.S. Patent No. 6,773,564.

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8. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) (“Akio”), Yamauchi et al. (US 6,218,134) (“Yamauchi”) and the CAPLUS abstract of Kurtinaitiens et al. (“Mediated glucose biosensor based on PQQ-dependent glucose dehydrogenase,” *Biologija* (1995), (1-2), 50-2) (“Kurtinaitiens”). Claim 1, from which claim 5 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not mention providing a mediator. However, using a mediator in an electrochemical enzyme-based biosensor was common at the time of the invention. See Tables 1-3 (columns 19-24) in Yamauchi. In particular, it was known to use a mediator in a biosensor containing PQQ-dependent glucose dehydrogenase. See Kurtinaitiens. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a mediator as taught by Kurtinaitiens in the invention of claim 7 of U.S. Patent No. 6,773,564 because a mediator is necessary to transfer an electron from the signal substance (enzyme) to the electrode to indicate that the enzyme has acted on an analyte molecule (col. 21:16-36 of Yamauchi).

9. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 4, 7, 51, 63, and 72 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) (“Akio”). Claim 2, from which claim 6 depends, has been addressed above. Claim 4 of U.S. Patent No. 6,773,564 requires a calcium salt stabilizer. Note that although claim 2 of U.S. Patent

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No. 6,773,564 only refers to “a” stabilizer which can be construed as only one stabilizer; that is gluconic acid or a calcium salt, it is clear from related claims 51, 63, and 72 in U.S. Patent No. 6,773,564 that having more than one stabilizer in the reagent layer as contemplated, as these claims refer to “at least one” stabilizer.

10. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) (“Akio”). Claim 2, from which claim 7 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564 requires the reaction layer to contain gluconic acid, but does mention gluconic salts. As noted in the rejection of claim 1, Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also discloses that a gluconic salt, such as a sodium or potassium salt of gluconic acid may be used. See claim 4 of Akio. Since Akio discloses using a sodium or potassium salt of gluconic acid to preserve a glucose enzyme in a biosensor it would have been obvious to one with ordinary skill in the art at the time of the invention to also consider using it in the invention of claim 7 of U.S. Patent No. 6,773,564.

11. Claim 8 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) (“Akio”). Claim 3, from which claim 8

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depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564 requires the reaction layer to contain gluconic acid, but does mention gluconic salts. As noted in the rejection of claim 1, Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also discloses that a gluconic salt, such as a sodium or potassium salt of gluconic acid may be used. See claim 4 of Akio. Since Akio discloses using a sodium or potassium salt of gluconic acid to preserve a glucose enzyme in a biosensor it would have been obvious to one with ordinary skill in the art at the time of the invention to also consider using it in the invention of claim 7 of U.S. Patent No. 6,773,564.

12. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"), Yamauchi et al. (US 6,218,134) ("Yamauchi") and the CAPLUS abstract of Kurtinaitiens et al. ("Mediated glucose biosensor based on PQQ-dependent glucose dehydrogenase," *Biologija* (1995), (1-2), 50-2) ("Kurtinaitiens"). Claim 2, from which claim 9 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not mention providing a mediator. However, using a mediator in an electrochemical enzyme-based biosensor was common at the time of the invention. See Tables 1-3 (columns 19-24) in Yamauchi. In particular, it was known to use a mediator in a biosensor containing PQQ-dependent glucose

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dehydrogenase. See Kurtinaitiens. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a mediator as taught by Kurtinaitiens in the invention of claim 7 of U.S. Patent No. 6,773,564 because a mediator is necessary to transfer an electron from the signal substance (enzyme) to the electrode to indicate that the enzyme has acted on an analyte molecule (col. 21:16-36 of Yamauchi).

13. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"), Yamauchi et al. (US 6,218,134) ("Yamauchi") and the CAPLUS abstract of Kurtinaitiens et al. ("Mediated glucose biosensor based on PQQ-dependent glucose dehydrogenase," *Biologija* (1995), (1-2), 50-2) ("Kurtinaitiens"). Claim 4, from which claim 11 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not mention providing a mediator. However, using a mediator in an electrochemical enzyme-based biosensor was common at the time of the invention. See Tables 1-3 (columns 19-24) in Yamauchi. In particular, it was known to use a mediator in a biosensor containing PQQ-dependent glucose dehydrogenase. See Kurtinaitiens. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a mediator as taught by Kurtinaitiens in the invention of claim 7 of U.S. Patent No. 6,773,564 because a mediator is necessary to transfer an electron from the signal substance (enzyme) to the electrode to indicate that the enzyme has acted on an analyte molecule (col. 21:16-36 of Yamauchi).

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14. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 4 and 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"), Yamauchi et al. (US 6,218,134) ("Yamauchi") and the CAPLUS abstract of Kurtinaitiens et al. ("Mediated glucose biosensor based on PQQ-dependent glucose dehydrogenase," *Biologija* (1995), (1-2), 50-2) ("Kurtinaitiens"). Claim 3, from which claim 10 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not mention providing a mediator. However, using a mediator in an electrochemical enzyme-based biosensor was common at the time of the invention. See Tables 1-3 (columns 19-24) in Yamauchi. In particular, it was known to use a mediator in a biosensor containing PQQ-dependent glucose dehydrogenase. See Kurtinaitiens. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a mediator as taught by Kurtinaitiens in the invention of the combination of claims 4 and 7 of U.S. Patent No. 6,773,564 because a mediator is necessary to transfer an electron from the signal substance (enzyme) to the electrode to indicate that the enzyme has acted on an analyte molecule (col. 21:16-36 of Yamauchi).

15. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564). Claim 7 of U.S. Patent No. 6,773,564 meets all of the limitations of claim 1 of the instant application except that claim 7, nor any other claim in U.S. Patent No. 6,773,564, does not require the glucose sensor response after being immediately fabricated to be substantially the same as compared after being

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stored for one week at 40°C. However, since the structure and the composition of the claimed biosensor is the same as that of Claim 7 of U.S. Patent No. 6,773,564 it should have the same properties, unless there is an unclaimed critical reaction layer ingredient.

16. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 12, from which claim 13 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not require the glucose sensor to be in a sealed container. Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of claim 12 of the instant application because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The sealed container will also prevent the reaction layer from being contaminated or wetted.

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17. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 12, from which claim 14 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not require the specified ranges for the amount of gluconic acid and for the amount of glucose dehydrogenase; however, barring evidence to the contrary, such as unexpected results, the amount of glucose dehydrogenase will be proportional to the expected sample size (amount of analyte) and the amount of gluconic acid, since it is a stabilizer, will be proportional to the amount of glucose dehydrogenase.

18. Claim 15 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio"). Claim 1, from which claim 15 depends, has been addressed above. Claim 7 of U.S. Patent No. 6,773,564, nor any other claim in U.S. Patent No. 6,773,564, does not require the specified ranges for the amount of gluconic acid and for the amount of glucose dehydrogenase; however, barring evidence to the contrary, such as unexpected results, the amount of glucose dehydrogenase will be proportional to the expected sample size (amount of analyte) and the amount of gluconic acid, since it is a stabilizer, will be proportional to the amount of glucose dehydrogenase.

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19. Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,773,564 in view of the English language translation of Akio et al. (JP 09-262086 A) (“Akio”). Claim 7 of U.S. Patent No. 6,773,564 meets all of the limitations of claim 16 of the instant application.

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

21. Claims 12 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Yugawa et al. (US 6,773,564 B1) (“Yuguwa”).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

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Addressing claim 12, Yugawa discloses all of the limitations of claim 12 (see claim 7 of Yugawa) except for whether the glucose sensor response after being immediately fabricated is substantially the same as compared after being stored for one week at 40°C. However, since the structure and the composition of the claimed biosensor is the same as that of claim 7 of Yugawa it should have the same properties, unless there is an unclaimed critical reaction layer ingredient.

Addressing claim 16, Yugawa discloses all of the limitations of claim 16. See claim 7 of Yugawa.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claims 1-4, 6-8, and 13-15 are rejected under 35 U.S.C. 103(a) as being obvious over Yugawa et al. (US 6,773,564 B1) ("Yuguwa") in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio").

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

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accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Addressing claim 1, Yugawa discloses all of the limitations of claim 1 except for having the glucose in a sealed container. See claim 7 of Yugawa. Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*. Akio also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of Yugawa because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The sealed container will also prevent the reaction layer from being contaminated or wetted.

Addressing claim 2, Claim 7 of Yugawa requires the reaction layer to contain phthalic acid.

Addressing claim 3, Claim 4 of Yugawa requires the reaction layer to contain a calcium salt.

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Addressing claims 4, 7, and 8, as noted in the rejection of claim 1, Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*). Akio also discloses that a gluconic salt, such as a sodium or potassium salt of gluconic acid may be used. See claim 4 of Akio. Since Akio discloses using a sodium or potassium salt of gluconic acid to preserve a glucose enzyme in a biosensor it would have been obvious to one with ordinary skill in the art at the time of the invention to also consider using it in the invention of Yugawa.

Addressing claim 6, Claim 4 of Yugawa requires the reaction layer to contain a calcium salt. Note that although claim 2 of Yugawa only refers to “a” stabilizer which can be construed as only one stabilizer; that is gluconic acid or a calcium salt, it is clear from related claims 51, 63, and 72 in Yugawa that having more than one stabilizer in the reagent layer as contemplated, as these claims refer to “at least one” stabilizer. Also see col. 6:36-41 in Yugawa.

Addressing claim 13, Yugawa discloses all of the limitations of claim 12 (see claim 7 of Yugawa) except for whether the glucose sensor response after being immediately fabricated is substantially the same as compared after being stored for one week at 40°C. However, since the

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structure and the composition of the claimed biosensor is the same as that of claim 7 of Yugawa it should have the same properties, unless there is an unclaimed critical reaction layer ingredient.

As for the glucose sensor being in a sealed container, Akio discloses a biosensor that has an electrode system and a reaction layer that includes glucose dehydrogenase and gluconic acid (the abstract; *Technical Field*; and paragraphs [0014]-[0016] of *Means*. Akio also teach storing the sensor in a sealed container (claim 4, paragraph [0017] of *Means*, and paragraph [0024] of *Example*). It would have been obvious to one with ordinary skill in the art at the time the invention was made to store the glucose sensor in a sealed container as taught by Akio in the invention of Yugawa because this will further help preserve the reaction layer paragraph [0017] of *Means* in Akio). The sealed container will also prevent the reaction layer from being contaminated or wetted.

Addressing claim 14, Yugawa discloses all of the limitations of claim 12 (see claim 7 of Yugawa) except for whether the glucose sensor response after being immediately fabricated is substantially the same as compared after being stored for one week at 40°C. However, since the structure and the composition of the claimed biosensor is the same as that of claim 7 of Yugawa it should have the same properties, unless there is an unclaimed critical reaction layer ingredient.

As for the specified ranges for the amount of gluconic acid and for the amount of glucose dehydrogenase, barring evidence to the contrary, such as unexpected results, the amount of glucose dehydrogenase will be proportional to the expected sample size (amount of analyte) and the amount of gluconic acid, since it is a stabilizer, will be proportional to the amount of glucose dehydrogenase.

Addressing claim 15, as for the specified ranges for the amount of gluconic acid and for the amount of glucose dehydrogenase, barring evidence to the contrary, such as unexpected results, the amount of glucose dehydrogenase will be proportional to the expected sample size (amount of analyte) and the amount of gluconic acid, since it is a stabilizer, will be proportional to the amount of glucose dehydrogenase.

26. Claims 5, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yugawa et al. (US 6,773,564 B1) ("Yuguwa") in view of the English language translation of Akio et al. (JP 09-262086 A) ("Akio") as applied to claims 1-4, 6-8, and 13-15 above, and further in view of Yamauchi et al. (US 6,218,134) ("Yamauchi") and the CAPLUS abstract of Kurtinaitiens et al. ("Mediated glucose biosensor based on PQQ-dependent glucose dehydrogenase," *Biologija* (1995), (1-2), 50-2) ("Kurtinaitiens").

Yugawa as modified by Akio does not mention providing a mediator. However, using a mediator in an electrochemical enzyme-based biosensor was common at the time of the invention. See Tables 1-3 (columns 19-24) in Yamauchi. In particular, it was known to use a mediator in a biosensor containing PQQ-dependent glucose dehydrogenase. See Kurtinaitiens. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use a mediator as taught by Kurtinaitiens in the invention of Yugawa as modified by Akio because a mediator is necessary to transfer an electron from the signal substance (enzyme) to the electrode to indicate that the enzyme has acted on an analyte molecule (col. 21:16-36 of Yamauchi).

Information Disclosure Statement

27. Applicants' Information Disclosure Statement (IDS) of April 11, 2004 has not been initialed because it is copy of the IDS of June 26, 2003, which was already considered. The examiner made the corrections desired by Applicants in hand to the IDS of June 26, 2003.

28. Applicants' IDS of April 16, 2004 and IDS of April 29, 2004 have not been initialed as they are copies of the IDS of April 01, 2004, which has been initialed.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Alex Noguera

Primary Examiner

AU 1753

December 16, 2004